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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/045,236	03/20/98	SANKARAM	M 07333/022002
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HM21/0928

EXAMINER

ACHUTAMURTHY, P

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

09/28/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/045,236

Applicant(s)
M. Sankaram et al

Examiner
P. Achutamurthy

Group Art Unit
1648



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-34 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Drawings

The Drawing filed with the application is acceptable for examination and is approved by the PTO draftsman.

Specification

The disclosure is objected to because of the following informalities: .

The status of parent application No. 08/898,017 was not indicated in the Cross Reference to Related Applications on the first paragraph on page 1. Since this application has been abandoned, the examiner has inserted the phrase "now abandoned after the filing date (7/21/97) on line 2.

However, in view of the continuation data provided as the first paragraph on page 1 of the specification, it would appear that section 2 entitled "Description of Related Application" is redundant. Accordingly, it is suggested that this section be deleted and the remaining sections renumbered.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Rejection A

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to multivesicular liposomes (MLV) prepared by the recited method which comprises, among other steps, one step wherein a "first aqueous component is added in making a water-in-oil emulsion and another step wherein a "second aqueous" component is added. However, nowhere in the specification a re to be found a clear description what constitutes the "first aqueous component" and the "second aqueous component". An aqueous component would be a solution or a mixture of some substance or water-miscible solvent. But the actual aqueous components have not been disclosed with respect to their composition. It is not also clear if the first and second aqueous components are the same or different. Accordingly the specification lacks the requirement for written description under the 35 USC 122, statute.

Rejection B

Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The lack of adequate description of the aqueous components renders the claims

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nonenabled because without any guidance whatsoever to choose the aqueous components one having ordinary skill in the art would not be able to practice the invention because they would not know what to use as the aqueous component that would yield the multivesicular liposomes with the defined morphological characteristics. They also would not be able to indiscriminately use anything that contains water and reasonably expect to obtain the claimed liposomes.

Rejection C

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "nonhydrohalic acid" is vague and indefinite in the absence of specifying the intended acid.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to P., Achutamurthy whose telephone number is (703) 308-3804. The examiner can normally be reached on Monday-Thursday from 7:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald E. Adams, Ph.D., can be reached on (703) 308-0570. The fax phone number for this Group is (703) 308-4242.


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

pa
September 24, 1998


PONNATHAPURA ACHUTAMURTHY
PRIMARY EXAMINER
GROUP 1800